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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,420

Applicant(s)

ROORDA ET AL.

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19, 21-25 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/17/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Examiner notes the cancellation of non-elected claim 15.

Based on the newly-added claims, the following new restriction is required:

2. Newly submitted claims 26-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added claims are directed to coating a generic medical device by shaking within a pan, whereas the remaining original invention is directed to coating a stent by rotating in a horizontally-disposed drum.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Original remaining claims 16-19, newly-added dependent claims 21-25, and the new group of claims 33-37 are examined herein.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1, 3, and 7 under 35 U.S.C. 102(b) as being anticipated by De Leon et al. (4,952,419) has been withdrawn based on cancellation of the claims.

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4. The rejection of claims 1-3 and 7-14 under 35 U.S.C. 102(e) as being anticipated by Schwarz et al. (US 6,368,658 B1) has been withdrawn based on cancellation of the claims.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claims 1-14 and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (6,607,598) in view of Forster (4,581,242) has been withdrawn based on cancellation of claims 1-14 and amendment of claims 16-20.

As necessitated by Applicant's amendment, the following new rejection is applied:

7. Claims 16-19, 21-25, and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (6,607,598) in view of Gardner et al. (5,980,951).

As outlined in the previous office action, Schwarz '598 teaches a method of coating medical devices, such as stents, in a coating chamber using spray coating techniques. Schwarz '598 teaches that medical devices may be coated by his column spray coater or with pan-coating operations (col. 17, lines 35-40), but Schwarz fails to specifically teach the elements of a pan coating operation. It would have been obvious to one of ordinary skill in the art to look to the art of pan-coating for such elements to perform the operation disclosed by Schwarz '598.

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Gardner et al. is cited for teaching the coating of medical substrates with pan coating techniques or column spray coating techniques (col. 5, line 10).

The pan of Forster, with articles to be coated therein, is rotated horizontally about a rotating axis (col. 5, line 19). A coating substance is sprayed into the rotating pan onto the tumbling articles (col. 5, line 14).

Since Schwarz '598 teaches coating stents, which are small medical articles, in column spray or pan-coating operations and Gardner teaches coating small medical articles in column spray or pan-coating operations such that the use of a pan coater is accomplished by rotating horizontally about an axis, and spraying the coating composition therein, Gardner would have reasonably suggested the specifics of his pan-coating method in the pan-coating method of Schwarz. It would have been obvious to one of ordinary skill in the art to use the teachings of Gardner in the method of Schwarz to provide Schwarz '598 with a suitable procedure for pan coating small articles such as stents because Forster's method is suitable for small articles useful in the medical field where precise dosing and sterile conditions are required. Examiner also notes that both references teach the interchangeable use of column- and pan-coating spray methods for such operations.

Regarding claims 17-18 and 34, Schwarz teaches coating stents with polymers dissolved in solvents with active agents (col. 6, Example 1). Gardner also teaches spray-coating solutions.

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Regarding claims 19, 23, and 35 Schwarz '598 and Forster both teach the use of air blown into the coating pan.

Regarding the limitation of claims 21 and 37, requiring a specific rotation speed, it is Examiner's position that selection of an optimum rotation speed would have been within the skill of an ordinary artisan depending on the durability of the substrate, the number of articles contained within the pan, and the desired speed of coating.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 22, Schwarz teaches coating stents with agents that would inhibit restenosis (col. 4).

In example 1, Schwarz outlines a process in which the medical devices are subjected to air, a gaseous composition, at a temperature of 20-90 °C before the coating step, which heats the medical devices prior to coating, as required by claim 25 and provides air within the temperature range claimed by Applicant in claim 24. Additionally, Schwarz teaches a process temperature of 0-200 °C (col. 10, line 8), which would heat both the substrates and the air. Gardner also teaches heating the coating pan so that the coating dries soon after application (col. 5, line 16).

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Response to Arguments

8. In light of the amendments, Applicant's arguments, filed 2/17/2004, with respect to the Schwartz in view of Forster rejection have been fully considered and are persuasive. The rejection has been withdrawn in favor of the new rejection outlined above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen et al. teaches a method of pan coating medical implants

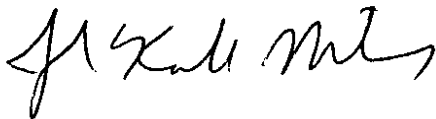
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using spraying and rotation, as outlined in the previous office action. Laube teaches pan-coating medical implants, as outlined in the previous office action. Williamitis teaches tumbling catheters with coating solution, as outlined in the previous office action. Cornelli et al. teaches spray coating medical articles in a horizontally-rotating drum/pan.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in black ink, appearing to read "J Kolb Michener".

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
May 20, 2004